

1    What is claimed is:

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3    1. A stented graft that can alternately include a compact configuration having a  
4       first diameter and an expanded configuration having a greater diameter,  
5       comprising, in combination:

6             at least one stent formed in a generally cylindrical shape having an  
7               outer surface and a hollow bore extending longitudinally therethrough,  
8               wherein said stent can alternately exist in a compact configuration

9               having a first diameter, and an expanded configuration having a  
10              greater diameter and a plurality of lateral openings; and,

11             a flexible, porous, biocompatible tubular elastomer covering having a  
12              first end, a second end, an outer surface and a hollow bore that  
13              extends longitudinally therethrough to define an inner surface;

14        said stent being deployed coaxially within said hollow bore of said covering  
15        such that said inner surface of said tubular covering is in contact with said outer  
16        surface of said stent.

17

18    2. The stented graft of claim 1 wherein said stent is

19        formed of a multiplicity of wire members that are braided into said generally  
20        cylindrical shape, and wherein said lateral openings in said stent are formed  
21        by gaps between adjacent wire members.

22

23    3. The stented graft according to claim 1, wherein said stent and said covering  
24        are anchored to each other by means for anchoring.

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2 4. The stented graft according to claim 2, wherein said stent and said covering  
3 are anchored to each other by at least one end of at least one said wire  
4 members that is fixidly embedded in said covering.

5

6 5. The tubular stented graft according to claim 3, wherein said tubular elastomer  
7 covering is anchored to said stent by means for anchoring comprising  
8 protrusions of said covering that fixidly protrude into said lateral openings in  
9 said stent.

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12 6. The stented graft of claim 1 wherein said elastomer covering is formed of an  
13 elastomer selected from the group consisting of polytetrafluoroethylene,  
14 fluorinated ethylene propylene, polytetrafluoroethylene-perfluoroalkyl vinyl  
15 ether copolymer, polyvinyl chloride, polypropylene, polyethylene  
16 terephthalate, broad fluoride; and, other biocompatable plastics.

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18  
19 7. The stented graft of claim 1 wherein said elastomer covering is formed of  
20 expanded, sintered PTFE tape, said tape having been wound about the outer  
21 surface of said stent to create said covering thereon.

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23 8. The stented graft of claim 6, wherein said polytetrafluoroethylene is expanded  
24 polytetrafluoroethylene having fibrils.

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1 9. The stented graft of claim 8, wherein said fibrils measure up to about 300  $\mu$  in  
2 length.

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4 10. The stented graft of claim 8, wherein said fibrils measure up to about 200  $\mu$  in  
5 length.

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7 11. The stented graft of claim 8, wherein said fibrils measure up to about 100  $\mu$  in  
8 length.

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10 12. The stented graft of claim 8, wherein said fibrils measure up to about 50  $\mu$  in  
11 length.

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13 13. The stented graft of claim 8, wherein said fibrils measure up to about 5  $\mu$  in  
14 length.

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16 14. The stented graft of claim 7 wherein said tape has a width of less than about  
17 1 inch.

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19 15. The stented graft of claim 7 wherein said tape has a thickness of less than  
20 0.015 inch and wherein said tape is wound about said stent in overlapping  
21 fashion, such that said elastomer covering comprises 1 to 10 layers of said  
22 tape.

23

1 16. The stented graft of claim 7 wherein said tape is helically wrapped  
2 about said stent.

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4 17. The stented graft of claim 7 wherein said tape has a width of 0.5  
5 inches (1.27 cm), and wherein said tape is helically wrapped such that 6-8  
6 revolutions of tape are applied per longitudinal inch (2.54 cm.) of said stented  
7 graft.

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9 18. The stented graft of claim 16 wherein said tape is helically wrapped  
10 alternately in a first direction and then in the opposite direction.

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12 19. The stented graft of claim 18 further comprising 8 layers of said tape.

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14 20. The stented graft of claim 1 wherein said stent is a self-expanding  
15 stent.

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17 21. The stented graft of claim 20, wherein said self-expanding stent  
18 comprises a shape memory alloy which can alternately exist in a first and a  
19 second crystalline state, wherein said stent assumes a radially  
20 expanded configuration when said shape memory alloy is in said first  
21 crystalline state, and a radially compact configuration  
22 when said shape memory alloy is in said second crystalline state.

23

1 22. The stented graft of claim 1 wherein said stent is a pressure-  
2 expandable stent.

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4 23. The stented graft of claim 22 wherein said stent is formed of  
5 a metal alloy wherein the alloying residue is iron and wherein the iron is  
6 alloyed with at least one other element selected from the group consisting  
7 of cobalt, chromium, nickel, and molybdenum.

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9 24. The stented graft of claim 21 wherein said shape memory alloy comprises at  
10 least about 51% to about 59% nickel and the remainder comprising titanium.

11

12 25. The stented graft of claim 21 wherein said shape memory alloy comprises  
13 about 0.25% chromium, at least about 51% to about 59% nickel, and the  
14 remainder comprising titanium.

15

16 26. The stented graft of claim 2 wherein some of said wire members of  
17 said stent are helically wound about a longitudinal axis in a first  
18 direction, and others of said wire members are helically wound about said  
19 longitudinal axis in a second direction such that they cross on opposite  
20 sides of the wire members which had been wound in the first helical  
21 direction, thereby forming a helically braided, cylindrical, wire stent.

22

23 27. The stented graft of claim 1 wherein said stent is formed of a

1        multiplicity of plastic members which are braided into said generally  
2        cylindrical shape, and wherein said lateral openings in the stent are  
3        formed by gaps which exist between adjacent plastic members.

4

5        28. The stented graft of claim 27 wherein said plastic members are formed  
6        of a plastic selected from the group consisting of polytetrafluoroethylene,  
7        fluorinated ethylene propylene, polytetrafluoroethylene-perfluoroalkyl vinyl  
8        ether copolymer, polyvinyl chloride, polypropylene, polyethylene  
9        terephthalate, broad fluoride, and, other biocompatible plastics.

10

11        29. The stented graft of claim 1 wherein said covering has a  
12        thickness of less than 0.1 inch (0.25 cm.)

13

14        30. The stented graft of claim 7 wherein said PTFE tape has a thickness  
15        of less than 0.015 inches (0.038 cm.), said tape being wrapped about said  
16        stent in overlapping fashion so as to form said covering.

17

18        31. The stented graft of claim 7 wherein said PTFE tape has a density of  
19        less than 1.6 g/cc.

20

21        32. The stented graft of claim 7 wherein said covering has a thickness of less  
22        than 0.1 inch (0.25 cm.) and the PTFE tape has a density of less than 1.6  
23        g/cc.

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2 33. The stented graft of claim 1 wherein said stent further comprises a polymer  
3 coating formed on said stent.

4

5 34. The stented graft of claim 33 wherein the polymer coating formed on  
6 said stent is of a polymer material selected from the group consisting of  
7 polytetrafluoroethylene, fluorinated ethylene propylene,  
8 polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer, polyvinyl  
9 chloride, polypropylene, polyethylene terephthalate, polyvinylidene fluoride,  
10 and, other biocompatible plastics.

11

12 35. The stented graft of claim 33 wherein said polymer coating was  
13 applied to said stent by the steps of:

14     □ immersing said stent in a liquid polymer dispersion;  
15     □ removing said stent from said liquid polymer dispersion; and,  
16     □ drying said liquid polymer dispersion that has remained on said stent,  
17 whereby said polymer coating is formed on said stent.

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19 36. The stented graft of claim 33 wherein said polymer coating is formed  
20 by electron beam deposition.

21

22 37. The stented graft of claim 33 wherein said stent comprises a  
23 plurality of elongate members, and wherein said polymer coating is formed

1 on said elongate members by positioning a polymer tube around each  
2 elongate member.

3

4 38. The stented graft of claim 33 wherein said tubular covering is adherent to  
5 said polymer coating.

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7 39. A method for the treatment of cardiovascular disease, comprising  
8 implanting the stented graft of claim 1 in a patient in need of such treatment  
9 wherein said implantation is effective to ameliorate one or more of the  
10 symptoms of said cardiovascular disease.

11

12 40. An article of manufacture, comprising packaging material and the stented  
13 graft of claim 1 contained within the packaging material, wherein said stented  
14 graft is effective for implantation in a patient afflicted with cardiovascular  
15 disease, and the packaging material includes a label that indicates that said  
16 device is effective for said implantation.

17

18 41. A stented graft that can alternately include a compact configuration having a  
19 first diameter and an expanded configuration having a greater diameter,  
20 comprising, in combination:

21  at least one stent formed in a generally cylindrical shape having an  
22 outer surface and a hollow bore extending longitudinally therethrough  
23 to form an inner surface, wherein said stent can alternately exist in a  
24 compact configuration having a first diameter, and an expanded

1 configuration having a greater diameter and a plurality of lateral  
2 openings; and,  
3     □ a tubular inner graft formed of an elastomer, said tubular inner graft  
4         having an outer surface and an inner surface, said tubular inner graft  
5         being deployed coaxially within said hollow bore of said stent; whereby  
6         said outer surface of said tubular inner graft is in contact with said  
7         inner surface of said stent.

8

9 42. The stented graft of claim 41 wherein said stent is formed of a multiplicity of  
10 wire members that are braided into said generally cylindrical shape, and  
11 wherein said lateral openings in said stent are formed by gaps between  
12 adjacent wire members.

13

14 43. The stented graft according to claim 41, wherein said stent and said tubular  
15 inner graft are anchored to each other by means for anchoring.

16

17 44. The stented graft according to claim 42, wherein said stent and said tubular  
18 inner graft are anchored to each other by at least one end of at least one said  
19 wire members that is fixidly embedded in said tubular inner graft.

20

21 45. The stented graft according to claim 42, wherein a plurality of lateral openings  
22 exist in said stent when said stent is at its radially expanded second diameter;  
23 and, said tubular inner graft is anchored to said stent by means for anchoring

1 comprising protrusions of said tubular inner graft that fixidly protrude into said  
2 lateral openings in said stent.

3

4 46. The stented graft of claim 41 wherein said elastomer is selected from the  
5 group consisting of polytetrafluoroethylene, fluorinated ethylene propylene,  
6 polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer, polyvinyl  
7 chloride, polypropylene, polyethylene terephthalate, broad fluoride; and, other  
8 biocompatable plastics.

9

10 47. The stented graft of claim 41 wherein said tubular inner graft is formed  
11 of PTFE.

12

13 48. The stented graft of claim 47, wherein said PTFE is expanded  
14 polytetrafluoroethylene having fibrils.

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16 49. The stented graft of claim 48, wherein said fibrils measure up to about 300  $\mu$   
17 in length.

18

19 50. The stented graft of claim 48, wherein said fibrils measure up to about 200  $\mu$   
20 in length.

21

22 51. The stented graft of claim 48, wherein said fibrils measure up to about 100  $\mu$   
23 in length.

1 52. The stented graft of claim 48, wherein said fibrils measure up to about 50  $\mu$  in  
2 length.

3

4 53. The stented graft of claim 48, wherein said fibrils measure up to about 5  $\mu$  in  
5 length.

6

7 54. The stented graft of claim 41 wherein said stent is a self-expanding  
8 stent.

9

10 55. The stented graft of claim 54, wherein said self-expanding stent  
11 comprises a shape memory alloy that can alternately exist in a first and a  
12 second crystalline state, wherein said stent assumes a radially expanded  
13 configuration when said shape memory alloy is in said first crystalline state, and  
14 a radially compact configuration when said shape memory alloy is in said second  
15 crystalline state.

16

17 56. The stented graft of claim 41 wherein said stent is a pressure-  
18 expandable stent.

19

20 57. The stented graft of claim 56 wherein said stent is formed of  
21 a metal alloy wherein the alloying residue is iron and wherein the iron is  
22 alloyed with at least one other element selected from the group consisting  
23 of cobalt, chromium, nickel, and molybdenum.

1

2 58. The stented graft of claim 55 wherein said stent is formed of  
3 a shape memory alloy comprising at least about 51% to about 59% nickel  
4 and the remainder comprising titanium.

5

6 59. The stented graft of claim 54 wherein said stent is formed of  
7 a shape memory alloy comprising about 0.25% chromium, at least about  
8 51% to about 59% nickel, and the remainder comprising titanium.

9

10 60. The stented graft of claim 42 wherein some of said wire members of  
11 said stent are helically wound about a longitudinal axis in a first  
12 direction, and others of said wire members are helically wound about said  
13 longitudinal axis in a second direction such that they cross on opposite  
14 sides of the wire members which had been wound in the first helical  
15 direction, thereby forming a helically braided, cylindrical, wire stent.

16

17 61. The stented graft of claim 41 wherein said stent is formed of a  
18 multiplicity of plastic members which are braided into said generally  
19 cylindrical shape, and wherein said lateral openings in the stent are  
20 formed by gaps which exist between adjacent plastic members.

21

22 62. The stented graft of claim 61 wherein said plastic members are formed  
23 of a plastic selected from the group consisting of polytetrafluoroethylene,

1 fluorinated ethylene propylene, polytetrafluoroethylene-perfluoroalkyl vinyl  
2 ether copolymer, polyvinyl chloride, polypropylene, polyethylene  
3 terephthalate, broad fluoride, and, other biocompatable plastics.

4

5 63. The stented graft of claim 41 further comprising a polymer coating formed on  
6 said stent.

7

8 64. The stented graft of claim 63 wherein said polymer coating is selected from  
9 the group consisting of polytetrafluoroethylene, fluorinated ethylene  
10 propylene, polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer,  
11 polyvinyl chloride, polypropylene, polyethylene terephthalate, polyvinylidene  
12 fluoride; and, other biocompatable plastics.

13

14 65. The stented graft of claim 63 produced by the steps of:

15  immersing said stent in a liquid polymer dispersion;  
16  removing said stent from said liquid polymer dispersion; and,  
17  drying said liquid polymer dispersion that has remained on said stent,

18 whereby said polymer coating is formed on said stent.

19

20 66. The stented graft of claim 63 wherein said polymer coating was formed  
21 on the stent by electron beam deposition.

22

23 67. The stented graft of claim 63 wherein said stent is formed of a

1       plurality of elongate members, and wherein said polymer coating was formed  
2       on said elongate members by positioning a polymer tube around each  
3       elongate member.

4

5       68. The stented graft of claim 63 wherein said tubular inner graft is adherent to  
6       said polymer coating on said stent.

7

8       69. A method for the treatment of cardiovascular disease, comprising  
9       implanting the stented graft of claim 41 in a patient in need of such treatment  
10      wherein said implantation is effective to ameliorate one or more of the  
11      symptoms of said cardiovascular disease.

12

13      70. An article of manufacture, comprising packaging material and the stented  
14      graft of claim 41 contained within the packaging material, wherein said  
15      stented graft is effective for implantation in a patient afflicted with congestive  
16      heart failure, and the packaging material includes a label that indicates that  
17      said stented graft is effective for said implantation.

18

19      71. An improved stented graft which is alternately deployable in a radially  
20      compact configuration having a first diameter and a radially expanded

1 configuration having a second diameter, said stented graft comprising:

2 • a stent comprising:

3     □ at least one member formed in a generally cylindrical shape having  
4             an outer surface and a hollow bore which extends longitudinally  
5             therethrough to define an inner surface;  
6     □ said stent being initially radially collapsible to a diameter which  
7             is substantially equal to said first diameter of the stented graft, and  
8             subsequently radially expandable to a diameter which is  
9             substantially equal to said second diameter of the stented graft;

10 and,

11     □ a plurality of lateral openings existing in said stent when said stent is  
12             at its radially expanded second diameter;

13 • a continuous, tubular PTFE covering formed on said stent, said PTFE  
14             covering comprising:

15     □ a tubular inner base graft formed of expanded, sintered PTFE, said  
16             tubular base graft having an outer surface and an inner surface, said  
17             tubular base graft being deployed coaxially within the hollow bore of  
18             said stent such that the outer surface of the tubular base graft is in  
19             contact with the inner surface of the stent, and the inner surface of  
20             said tubular base graft thereby defining a luminal passageway through  
21             the stented graft; and,

22     □ a tubular outer layer formed of expanded, sintered PTFE tape which  
23             has a width of less than about 1 inch, said tape having been wound  
24             about the outer surface of said stent to create said tubular outer layer

1                   thereon, such that said stent is captured between said outer layer and  
2                   said tubular base graft;  
3                   said tubular outer layer being attached to said tubular base graft,  
4                   through said lateral openings in said stent, to thereby form an integrally  
5                   stented, continuous PTFE tube which is alternately disposable in said  
6                   radially compact configuration of said first diameter and said radially  
7                   expanded configuration of said second diameter, wherein the improvement  
8                   comprises expanded, sintered PTFE having fibrils.  
9

10               72. The stented graft of claim 71, having said fibrils up to about 300  $\mu$  in length.

11

12               73. The stented graft of claim 71, having said fibrils up to about 200  $\mu$  in length.

13

14               74. The stented graft of claim 71, having said fibrils up to about 100  $\mu$  in length.

15

16               75. The stented graft of claim 71, having said fibrils up to about 50  $\mu$  in length.

17

18               76. The stented graft of claim 71, having said fibrils up to about 5  $\mu$  in length.

19

20               77. The stented graft of claim 71 wherein said stent is formed of  
21                   a shape memory alloy comprising at least about 51% to about 59% nickel and  
22                   the remainder comprising titanium.

23

24               78. The stented graft of claim 71 wherein said stent is formed of  
25                   a shape memory alloy comprising about 0.25% chromium, at least about 51%

1 to about 59% nickel, and the remainder comprising titanium.  
2

3 79. A method for the treatment of cardiovascular disease, comprising  
4 implanting the stented graft of claim 71 in a patient in need of such treatment  
5 wherein said implantation is effective to ameliorate one or more of the  
6 symptoms of said cardiovascular disease.

7  
8 80. An article of manufacture, comprising packaging material and the stented  
9 graft of claim 71 contained within the packaging material, wherein said  
10 stented graft is effective for implantation in a patient afflicted with  
11 cardiovascular disease, and the packaging material includes a label that  
12 indicates that said stented graft is effective for said implantation.

13